January 8, 1999

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

December 8, 1998

Mr. Philip Poli
Special Review and Reregistration Division
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-001

SUBJECT: Response to the Draft EFED and HED Reregistration Eligibility Decision (RED) Science Chapters for Disulfoton, List A Case 0102

Dear Mr. Poli:

Following is a response to the draft Environmental Fate and Effects Division (EFED) and Health Effects Division (HED) chapters for disulfoton which BAYER received from the EPA on November 9, 1998. Comments regarding the chapters and our plan for continued support for disulfoton are as follows:

Both chapters contain preliminary, screening-level calculations based on all "current" disulfoton labels. The review is therefore complicated by the fact that there are 90 "active" registrations for disulfoton-containing products, many of which are no longer being supported. To add to this, registrations for this efficacious active ingredient are held by more than 20 registrants and more than 100 active distributors.

The document describes the overall state of the reregistration efforts for disulfoton and with few exceptions, indicates that the current database is adequate to support continued registration of the chemical. The document goes on to indicate that there are no carcinogenicity concerns for disulfoton (classified as GROUP E), nor was there any evidence for increased susceptibility of disulfoton to infants or children. Finally, the document indicates that the additional 10X safety factor could be removed or lowered to 3X based on the toxicity data available for disulfoton. BAYER has found several areas which could be classified as errors of omission relative to the assessment of risk and are outlined below:

Errors to be Considered in the EFED Chapter

1. Results of life-cycle toxicity tests with *Daphnia magna* for the degradates disulfoton sulfoxide and sulfone were not included in the RED (page 25). The MRID numbers of the relevant studies are 43738002 and 43738001, respectively.

2. Use of predicted maximum residues values based on Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994) to estimate environmental concentrations (EECs) on avian and

mammalian food items for soil applied uses of disulfoton is clearly a misuse of the technique. It is clear that initial residues from direct foliar application of a pesticide are significantly higher then if a pesticide is applied directly to the soil. Hoerger and Kenaga, in their original article recognized that their "upper limit" residue values were inappropriate for direct soil applications. Urban and Cook (1986) in EPA's SEP for ecological risk assessment (Attachment J) also recognized that the use of this technique is "only appropriate for initial surface deposited residues ..." The draft RED therefore includes incorrect estimates of the maximum EEC for terrestrial food items for the soil applied uses of disulfoton. Field data for both foliar and soil application of disulfoton, has been reported in field studies (MRID # 410560-01 and 412018-01) conducted by Bayer Corporation and should be used.

3. PRZM/EXAMS exposure modeling did not include the default assumption where an aerobic aquatic metabolism half-life is set to 2x the aerobic soil when an acceptable study does not exist and hydrolysis is presumed stable. References for the use of 2x the aerobic soil rate:

   a. "Input Selection for Computer Modeling of Aquatic Pesticide Exposure Using the PRZM2 and EXAMS II Programs" Version 1.1 June 1995. USEPA Office of Pesticide Programs.

   b."Guidance for estimating metabolic degradation input parameters for GENEEC, PRZM and EXAMS when estimating exposure in surface water. Draft document by R. David Jones, April 28, 1998.

   Impact on the assessment: The aquatic values used in the ecotoxicology assessment are overestimated due to a lack of chemical reactivity in the farm pond. The exposure assessment also cannot be used in a reliable drinking water exposure assessment.

4. Di-Syston application details to crops used in exposure modeling are not correct. For example, the application of Di-Syston 15G to tobacco assumes 12-inch row spacing. This is not possible in a commercial field and does not reflect reasonable agriculture.

   Impact on the assessment: The aquatic exposure values used in the ecotoxicology assessment are overestimated due to unreasonable interpretations of the product label for the crops investigated. The exposure assessment also cannot be used in a reliable drinking water exposure assessment. An aquatic exposure assessment study titled " An Aquatic Exposure Assessment of Disulfoton: Di-Syston Uses on Cotton, Potatoes and Wheat." (Bayer Report Number 107830, MRID # 44373101) was submitted to the Agency on September 8, 1997, and this study should be considered as a reference with respect to using reasonable agronomic practices.

5. The drinking water component of the aggregate risk was not brought into the FQPA risk assessment due to a full risk cup resulting from a Tier I dietary assessment. Appendix 6 of the HED RED describes a drinking water assessment based on Tier II PRZM/EXAMS modeling. The OPP stated previously that results of these models using a stagnant pond should not be used in the assessments:

"OPP wishes to emphasize that the GENEEC and PRZM/EXAMS modeling of an edge of field farm pond is not appropriate for generating accurate estimates of pesticides or degradates in actual drinking water, and **should not be used directly in computing aggregate exposures for purposes of estimating human risks**." Reference: OPP's Interim Approach for Addressing Drinking Water Exposure. Memorandum from Stephen Johnson to OPP Division Directors, November 17, 1997.

Therefore, the Agency should not use the modeling results for FQPA exposure estimates, either in the form of estimating direct exposure or to suggest that concentrations predicted in water exceed a level of concern.

Impact on the assessment: Exposure estimates using PRZM/EXAMS modeling with a farm pond scenario should not be used to assess risk associated with drinking water. No relationship can be made between the resulting predictions and actual drinking water consumed by the American population.

6. HED RED on page 10 states that NAWQA data comprising 2700 surface water samples are limited for use in an exposure assessment because there are "no data on disulfoton use in the area surveyed". In fact, NAWQA has published a national map of product use (http:/water.wr.usgs.gov/pnsp/use92/dislfotn.html) which shows that 5 of the study units with primary monitoring completed are in the high use areas for di-syston. (NAWQA study units 22, 23, 48, 50 and 56). Therefore, the correspondence between product use and resulting surface water quality is captured. A maximum observation of 0.04 ppb observed in agricultural streams is believed to represent an upper bound concentration of disulfoton in small streams located in agricultural areas.

   NAWQA also analyzed 2200 ground water samples with no detections. The program was run using a single analytical method for this analyte with a reported limit of quantitation of 0.01 ppb. Thus, there exists a very large database of both surface and ground water in which a single method of quantified performance was used.

   Impact on the assessment: NAWQA monitoring data which are published with supporting product use and analytical method performance standards should be evaluated as reliable information regarding potential source water for drinking. Finished drinking water should be assumed to have no higher residues than was measured in this program.

Errors to be Considered in the HED Chapter

The only deficiency noted in this chapter is in the area of plant metabolism. The Agency asked for additional information to upgrade the existing studies on lettuce, potatoes, soybeans, and wheat. This request is based on an EPA memorandum dated March 18, 1997, entitled Disulfoton (032501), Reregistration case 102 (CBRS No. 13715, DP Barcode No. D203210, MRID # 43222401) from John Abbotts to Paula Deschamp.

Bayer has already responded to this request with the submission of Bayer Report No. 107834

(MRID # 44342101) dated 7/24/97. As this report is already in the Agency's files, failure to include it in this review constitutes an error of omission.

The document suggests several areas for exposure reduction and the need for additional data. BAYER will work with the Agency over the several months to define which uses will be supported, discuss the various mitigation measures proposed and further refine the risk assessment of disulfoton. Additionally, BAYER has already initiated studies in several areas to cover the need for additional information suggested by the Agency. These studies include:

a. An anaerobic aquatic or anaerobic soil metabolism study and an aerobic aquatic metabolism study on disulfoton. BAYER is also considering studies that will characterize the fate of the sulfoxide and sulfone metabolites in soil and water.
b. A repeat acute neurotoxicity study in hens will be submitted by December 1999.
c. A Monte Carlo analysis for dietary exposure has been initiated and will be submitted within the next several months.
d. An updated material accountability study and the manufacturing information will be provided for the technical. BAYER will also provide the validated analytical methods for the 68% and 2% formulations by June 1999.

This represents BAYER's initial response to the HED and EFED chapters. Additional information concerning the risk assessment and supported uses will be provided during the public response period. As this information becomes available, BAYER will work with the Agency to refine the risk assessment for disulfoton and address issues and concerns raised by the Agency or FQPA. If you have any questions, please contact either me or Dr. Premjit Halarnkar at (816) 242-2331.

BAYER CORPORATION
AGRICULTURE DIVISION

John S. Thornton
Director, Product Registrations &
Regulatory Affairs

cc: George LaRocca (PM13)